FEB - 2 2001

K002237

510(k) SUMMARY

Device trade name: P^3IMRT^{TM}

Common name: Radiation Therapy Planning System

Classification name: Accelerator, Linear, Medical (per 21CFR section 892.5050)

Predicate Devices: Helax-TMS v5.0 K993766
Varian Helios Inverse Planning Module K984532
Nomos CORVUS Inverse Treament Planning System K940663

Device Description:

P^3IMRT^{TM} is an inverse planning IMRT option to the Pinnacle$^{3™}$ Radiation Therapy Planning Software (K993923). The Pinnacle$^{3™}$ system is composed of a Sun UNIX workstation running the Solaris operating system and software which provides the user with the capability to enter patient data into the system, use that data to construct a plan for radiation therapy, and evaluate the plan.

The P^3IMRT^{TM} software contains 4 components:

1) **Objective and constraint specification** – This allows the user to define the goals and limits for treatment targets and critical structures which guide the optimization process. The objectives or constraints can be based on dose or dose volume histogram specifications.
2) **Parameter selection** – This allows the user to specify the characteristics of the plan which may be modified during the optimization process, and is a variable in the treatment delivery.
3) **Optimization** – This is the process of iteratively adjusting the treatment parameters to create a plan that most closely complies with the objectives and constraints specified by the user.
4) **Conversion to delivery system** – This software converts the transmission values in the opening density matrix to the multileaf collimator or compensator for delivery.

Intended Use:
Pinnacle^3 Radiation Therapy Planning System with P^3IMRT^{TM} provides three-dimensional planning software for external beam (photons and electrons) and stereotactic radiosurgery planning.

Summary of Technological Characteristics Compared to Predicate Devices:
P^3IMRT^{TM} adds Inverse Planning IMRT capabilities to the existing Pinnacle^3 Radiation Therapy Planning System K993923. The Pinnacle^3 Radiation Therapy Planning System with P^3IMRT^{TM} incorporates no technological characteristics not currently contained in the predicate devices, Helax-TMS v5.0 (K993766), Varian Helios Inverse Planning Module (K984532) and Nomos CORVUS Inverse Treatment Planning System (K940663).

P^3IMRT^{TM} uses the convolution superposition algorithm as the final dose engine, whereas the predicates use pencil beam, collapsed cone or pencil beam convolution algorithms. P^3IMRT^{TM} and the predicates use different optimization algorithms. P^3IMRT^{TM} does not require a standalone optimization tool as do two of the predicate devices; all P^3IMRT^{TM}/Pinnacle^{3TM} functionality is contained in one integrated workstation.

Summary of Non-clinical Tests

A Hazard Analysis was completed for the P^3IMRT^{TM} option, and hazards mitigated as appropriate. Verification and Validation test plans were completed in compliance with ADAC Laboratories procedures, and will be utilized to demonstrate that the P^3IMRT^{TM} option has met its specifications, demonstrates substantially equivalent performance to the predicate devices, and is safe and effective for its intended use.

Summary of Clinical Tests

Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness.

Conclusions

The Pinnacle^3 Radiation Therapy Planning System with P^3IMRT^{TM} is substantially equivalent to the predicate devices. It has the same intended use as the predicates, and its use does not raise any new or different issues of safety or effectiveness when compared to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2001

Janice E. Brown
ADAC Laboratories
ADACLABO
540 Alder Dr.
MILPITAS CA 95035

Re: K002237
P3IMRT
Dated: December 14, 2000
Received: December 15, 2000
Regulatory Class: II
21 CFR §897.5050/Procode: 90 MUJ

Dear Ms. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510 (k) NUMBER (IF KNOWN): K002237

DEVICE NAME: P^{3}IMRT™

INDICATIONS FOR USE:

Pinnacle^{3}™ Radiation Therapy Planning Software with P^{3}IMRT™ is a computer software package intended to provide support for radiation therapy treatment planning for the treatment of benign or malignant disease processes.

P^{3}IMRT™ assists the clinician in formulating a treatment plan that maximizes the dose to the treatment volume while minimizing the dose to the surrounding normal tissues.

The device is indicated for use in patients deemed to be acceptable candidates for radiation treatment in the judgment of the clinician responsible for patient care.

Plans generated using this software are used in the determination of the course of a patient's radiation treatment. They are to be evaluated, modified and implemented by qualified medical personnel.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002237